IN THE CLAIMS

This listing of claims replaces all prior versions, and listings, in this application.

1. (previously presented) A pharmaceutical formulation comprising: (a) an effective amount of levothyroxine sodium, (b) microcrystalline cellulose which has a mean particle size of less than 125 μm and is present in an amount of 60 to 85% w/w based upon the total weight of the formulation, and (c) pregelatinised starch present in an amount of 5 to 30% w/w based upon total weight of the formulation; wherein the pregelatinised starch is produced by subjecting moistened starch to mechanical pressure in order to rupture some or all of its starch granules and subsequent drying.

2. (previously presented) The pharmaceutical formulation as claimed in claim 1 wherein the microcrystalline cellulose has a mean particle size less than or equal to 100 μm.

3. (previously presented) The pharmaceutical formulation as claimed in claim 2 wherein the ratio of microcrystalline cellulose:pregelatinised starch is in the range of 2:1 to 15:1.

4. (previously presented) The pharmaceutical formulation as claimed in claim 3 wherein the microcrystalline cellulose and pregelatinised starch comprise water which is present in an amount 3-6% w/w based on the total weight of the formulation.

5. (previously presented) The pharmaceutical formulation as claimed in claim 1 wherein the levothyroxine sodium is hydrated.

6. (previously presented) The pharmaceutical formulation as claimed in claim 5 wherein the levothyroxine sodium is the pentahydrate form.

7. (previously presented) The pharmaceutical formulation as claimed in claim 1 which further comprises one or more glidant/lubricants.

8. (previously presented) The pharmaceutical formulation as claimed in claim 7 wherein the glidant/lubricants are selected from the group consisting of colloidal anhydrous silica, talc, magnesium stearate, and mixtures thereof.

9. (previously presented) The pharmaceutical formulation as claimed in claim 1 which is stable to the extent that potency decreases by less than 5% when the pharmaceutical formulation is stored at 25°C and 60% relative humidity for 12 months.

10. (previously presented) The pharmaceutical formulation as claimed in claim 1 in unit dose form.

11. (previously presented) The pharmaceutical formulation as claimed in claim 10 wherein the unit dose form is a tablet.

Claims 12-14 (canceled)

15. (withdrawn) A method of treating thyroid hormone disorders comprising administering a pharmaceutical formulation as claimed in claim 1 to a mammal.

16. (withdrawn) A process for preparing a pharmaceutical formulation as claimed in claim 1 comprising (a) preparing a triturate of levothyroxine sodium, (b) mixing the triturate with remaining components of the pharmaceutical formulation, and (c) compressing the mixture of triturate and remaining components.

17. (withdrawn) The method of claim 15 wherein said mammal is a human.

18. (previously presented) The pharmaceutical formulation as claimed in claim 10 wherein the unit dose form is a 50 µg tablet which comprises: 0.0425-0.0575 mg levothyroxine sodium, 50-60 mg microcrystalline cellulose, 12-17 mg pregelatinised

starch, 2-3 mg talc, 1-2 mg colloidal anhydrous silica and 0.5-1.0 mg magnesium stearate.

19. (previously presented) The pharmaceutical formulation as claimed in claim 10 wherein the unit dose form is a 100 µg tablet which comprises: 0.085-0.115 mg levothyroxine sodium, 100-120 mg microcrystalline cellulose, 24-34 mg pregelatinised starch, 4-6 mg talc, 2-4 mg colloidal anhydrous silica and 1-2 mg magnesium stearate.

20. (previously presented) A pharmaceutical formulation comprising: (a) an effective amount of levothyroxine sodium, (b) microcrystalline cellulose which has a mean particle size of less than 125 µm and is present in an amount of 60 to 85% w/w based upon the total weight of the formulation, and (c) pregelatinised starch present in an amount of 5 to 30% w/w based upon total weight of the formulation; wherein the pregelatinised starch contains about 5% free amylase, 15% free amylopectin, and 80% unmodified starch.

21. (new) A pharmaceutical formulation comprising: (a) an effective amount of levothyroxine sodium, (b) microcrystalline cellulose which has a mean particle size of less than 125 µm and is present in an amount of 60 to 85% w/w based upon the total weight of the formulation, and (c) pregelatinised starch present in an amount of 5 to 30% w/w based upon total weight of the formulation; wherein the pregelatinised starch is produced by subjecting moistened starch to mechanical pressure in order to rupture some or all of its starch granules and subsequent drying; and wherein the pharmaceutical formulation has a water content of at least 3% w/w based upon total weight of the formulation.

22. (new) The pharmaceutical formulation as claimed in claim 21 wherein the microcrystalline cellulose has a mean particle size less than or equal to 100 µm.

23. (new) The pharmaceutical formulation as claimed in claim 22 wherein the ratio of microcrystalline cellulose:pregelatinised starch is in the range of 2:1 to 15:1.

24. (new) The pharmaceutical formulation as claimed in claim 23 wherein the microcrystalline cellulose and pregelatinised starch comprise water which is present in an amount 3-6% w/w based on the total weight of the formulation.

25. (new) The pharmaceutical formulation as claimed in claim 21 wherein the levothyroxine sodium is hydrated.

26. (new) The pharmaceutical formulation as claimed in claim 21 which further comprises one or more glidant/lubricants.

27. (new) The pharmaceutical formulation as claimed in claim 21 which is stable to the extent that potency decreases by less than 5% when the pharmaceutical formulation is stored at 25°C and 60% relative humidity for 12 months.

28. (new) The pharmaceutical formulation as claimed in claim 21 in unit dose form.

29. (new) The pharmaceutical formulation as claimed in claim 28 wherein the unit dose form is a tablet.

30. (new) A method of treating thyroid hormone disorders comprising administering a pharmaceutical formulation as claimed in claim 21 to a mammal.

31. (new) A process for preparing a pharmaceutical formulation as claimed in claim 21 comprising (a) preparing a triturate of levothyroxine sodium, (b) mixing the triturate with remaining components of the pharmaceutical formulation, and (c) compressing the mixture of triturate and remaining components.

32. (new) The method of claim 31 wherein said mammal is a human.

33. (new) The pharmaceutical formulation as claimed in claim 28 wherein the unit dose form is a 50 µg tablet which comprises: 0.0425-0.0575 mg levothyroxine sodium, 50-60 mg microcrystalline cellulose, 12-17 mg pregelatinised starch, 2-3 mg talc, 1-2 mg colloidal anhydrous silica and 0.5-1.0 mg magnesium stearate.

34. (new) The pharmaceutical formulation as claimed in claim 28 wherein the unit dose form is a 100 µg tablet which comprises: 0.085-0.115 mg levothyroxine sodium, 100-120 mg microcrystalline cellulose, 24-34 mg pregelatinised starch, 4-6 mg talc, 2-4 mg colloidal anhydrous silica and 1-2 mg magnesium stearate.